

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of.:	§	
	§	
Lola WEISS et al	§	
	§	Confirmation No.: 3826
Serial No.: 10/589,623	§	
	§	
Filed: August 16, 2006	§	Group Art Unit: 1628
	§	
For: TREATING OR	§	
PREVENTING DIABETES	§	
WITH CANNABIDIOL	§	
	§	Attorney Docket: 32361
Examiner: Jennifer M. KIM	§	

DECLARATION OF RUTH GALLILY UNDER 37 CFR 1.132

I am presently employed as researcher at the Lautenberg Center of Immunology the Hebrew University-Hadassah medical school, Jerusalem, where I am a a Emeritus professor. I received my Ph.D degree from the Hebrew University in 1956, worked as a post-doctoral fellow in Sloan-Kettering Institute, NY, USA; Research Associate in Johns Hopkins University Baltimore USA; California Institute of Technology, USA and was a visiting Professor at UCLA and USCF, CA ,USA

My research focuses mainly on Immune mechanism, especially on Innate immunity. Since the beginning of my career, I have published 154 scientific articles in highly regarded journals and books, and have presented my achievements at many international scientific conferences.

I am a member of Society of Sigma Xi, CIT Chapter; Israel Immunology Society; Society of Leukocyte Biology (Honorary Life membership); International Cytokine Society; and International Cannabinoid Society, was awarded Honorary Life Membership of the Society for Leukocyte Biology and life Membership in John Hopkins Society for Scholars.

I am a co-inventor of the subject matter claimed in the above-referenced U.S. patent application.

I have read the Official actions issued with respect to the above-identified application.

In this official action the Examiner has rejected claims 1-5, 8-10, 24 and 26 under 35 U.S.C 103, as being unpatentable over R&D Profile of record (2003) in view of Spevak (7,071,231) and Gorter (1999).

The Examiner specifically states that R&D profile teaches the D9 THC and CBD have been employed in a clinical trial of peripheral neuropathy secondary to diabetes mellitus. Spevak et al. teach that Type II is the most prevalent form of diabetes and Gorter teaches that CBD antagonizes the psychotropic actions of THC. Therefore the skilled in the art would use the composition described in the R&D profile for the treatment of T2DM given the excellent safety data and the absence of psychotropic activity as taught by Gorter.

Being an expert in the field of CBD and cannabis-based medicine, as evidenced by the attached list of publications in peer reviewed journals, I hereby declare that the THC:CBD composition employed in the R&D profile publication, is characterized by psychotropic activity.

In evidence to that I refer the Examiner to:

1. the R&D profile publication showing that the THC:CBD composition was registered as Sativex^R. See Table II page 309 of the R&D Profile. XXX-THIS IS THE WEAKEST POINT
2. the substrate product characteristics (SPC, attached herewith) of Sativex published by GWPharmaceuticals showing that Sativex has psychotropic effects.

Psychiatric symptoms such as anxiety, illusions, changes in mood, and paranoid ideas have been reported during treatment with Sativex. These are likely to be the result of transient CNS effects and are generally mild to moderate in severity and well tolerated. They can be expected to remit on reduction or interruption of Sativex medication.

In view of the above, it is my expert opinion that the compound disclosed by the R&D profile publication is psychoactive and therefore can't be used to anticipate or render obvious the claimed invention.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

July 12, 2011



Prof. Ruth Gallily

Lautenberg Center of Immunology, the Hebrew University

Israel

Enc.:

CV of Prof. Gallily and List of publications

Sativex SPC

Ruth Gallily
CURRICULUM VITAE

<u>Citizenship:</u>	Israeli
<u>Family Status:</u>	Widow, 3 children
<u>Military Service:</u>	1947 – 1948: War of Independence
<u>Education:</u>	
1957-1958	Postdoctoral Research Associate, Dept. of Biochemistry, University of Illinois, Urbana, Illinois
1956-57	Postdoctoral Research Associate, Sloan Kettering Institute, New York
1956	Ph.D. The Hebrew University of Jerusalem and Weizmann Institute of Science, Rehovot
	Thesis: Genetics of Tumor Transplantation
1952	M.Sc. in Biology & Biochemistry, Hebrew University of Jerusalem
1945	Reali High School
<u>Employment:</u>	
1995-present	Professor Emeritus
1993 (3 months)	Visiting Professor; Dept. of Radiation Therapy, The Sloan Kettering Institute, New York
1993 (3 months)	Short-term member of Wolfson College, Oxford and Dunn School of Pathology; Oxford, England
1989-1990	Visiting Professor, Dept. of Cell Physiology and Immunology, The Rockefeller University, New York
1982-1983	Visiting Professor, Department of Microbiology and Immunology UCSF, San Francisco, California
1979-present	Professor of Immunology, Lautenberg Center
1979	Visiting Investigator, Sloan-Kettering Institute, New York
1977-1978	Visiting Associate Professor, Department of Microbiology and Immunology, UCLA. Los Angeles, California
1976-1979	Associate Professor, Department of Immunology, Hebrew University of Jerusalem
1971-1976	Senior Lecturer, Department of Immunology, Hebrew University of Jerusalem
1967-1969	Research Fellow, Immunochemistry, California Institute of Technology, Pasadena, California
1964-1967	Research Associate, Department of Cell Biology, Weizmann Institute of Science, Rehovot
1962-1964	Research Associate, School of Hygiene and Public Health, Johns Hopkins University, Maryland
1959-1962	Research Associate, Weizmann Institute of Science, Rehovot
<u>Honors</u>	
1995	Life-time Membership in Johns Hopkins Society for Scholars
1992	Honorary Life Membership of the Society for Leukocyte Biology
<u>Membership in Professional Societies:</u>	
	Society of Sigma Xi, CIT Chapter
	Israel Immunological Society
	Society of Leukocyte Biology (Honorary Life Membership)
	European Reticuloendothelial Society (EURES)
	European Association for Cancer Research
	International Cytokine Society (ICS)
	International Cannabinoid Society (ICRS)